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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,151	10/27/2003	Stephen C. Porter	03-116 (US01)	6462

41696 7590 03/10/2009

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
03/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,151	PORTER, STEPHEN C.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20-30,32-38 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 20-30, 32-38, 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 14-16, 20, 21, 24, 27, 30, 31, 34-36 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken (US 6,193,728) in view of Kupiecki (US 5,669,931) in view of Rosenthal (US 7,066,904)

3. Ken discloses vaso-occlusive device comprising an elongate occlusive member (102,202), which is a coil defining a longitudinal axis having an elongate axial lumen and an active element (108,214) having a pre-deployment configuration carried entirely within the lumen. No portion of the pre-deployed active element is located outside of the lumen. The active element is configured to cause the occlusive member to substantially retain its shape when deployed. The active element is secured to the occlusive member by an adhesive at one or both ends and at one or more locations along the length of the occlusive member (Col 5, lines 1-3). The active element has an elongate shape (Fig 1A) and a coil shape (Fig. 1C). The active element comprises shape memory alloy or a shape memory polymer (Col 5, line 31 and Col 6, line 46-48). The active element can be a fiber comprising protein (Col 6, line 64).

4. Ken does not disclose that the active element contracts.

5. However, Kupiecki teaches a vaso-occlusive device where the interior is filled with a drug material that can be advantageous for inducing thrombism or for treating surrounding tissue (C 6: L 11-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug into the device of Ken to achieve the same advantages.

6. Rosenthal teaches that one method of drug delivery incorporates immobilizing a drug within a hydrogel to control the release of the drug (C1: L47-59). The hydrogel can expand or contract in order to release the drug (bioactive agent) (Col 6, line 55-64). The hydrogel is a polymer hydrogel that is swollen with an aqueous ionic solution that will diffuse out of the gel upon contact with blood (Col 2, lines 32-57). The polymer can be polymethacrylate (Col 3, line 37). The polymer is thermoresponsive (Col 3, line 60).

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydrogel for carrying a drug within the lumen of the occlusive coil as taught by Kupiecki and Rosenthal. Doing so would allow better control over the delivery of drugs for treating the tissue and inducing thrombism. The combination results in the device of Ken having an active element that is the combination of a stretch-resisting element (108) and the coating of the drug filled hydrogel. The hydrogel part of the active element will contract to a deployed configuration without the application of mechanical force when placed in the body to deliver the drug as taught by Rosenthal. The stretch resisting element part of the active element will cause the occlusive member to "substantially" retain its shape when deployed in a body cavity. Note that the claimed invention does not require the actual

act of the active element contracting to cause the coil to retain its shape since during the act of the active element contracting, the coil will also be moving and reshaping, thus not retaining its shape. Rather, the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape.

8. Claims 9-13, 22-26, 28, 29, and 36-38are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken (US 6,193,728) in view of Kupiecki (US 5,669,931) in view of Rosenthal (7,066,904) as applied above and further in view of Sawhney (US Pub 2001/0046518).

9. Ken modified by Kupiecki and Rosenthal discloses the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

10. Sawhney discloses a hydrogel used for delivery of therapeutic agents. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37, 38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35). The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergoes a thermally induced phase change or a pH induced phase change (Para 40). The active element is activated within about 10-20 minutes of being placed in a body (Para 28).

Ken modified by Kupiecki and Rosenthal provides the base of an occlusive coil with a core member that uses hydrogel to deliver bioactive agent. Sawhney provides the teaching of materials and characteristics of hydrogels. It would have been obvious to one having ordinary skill in the art at the time of the invention to enhance the modified device of Ken modified by Kupiecki and Rosenthal with the different materials and characteristics of hydrogels, since the teachings were made part of the ordinary capabilities of one skilled in the art based upon the teachings of Sawhney. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,*125 USPQ 416.

Response to Arguments

11. Applicant's arguments filed 11/07/08 have been fully considered but they are not persuasive. Applicant states that the combination of Ken, Kupiecki and Rosenthal does not result in a device having a stretch resistant member (active element) that contracts without the application of mechanical force to cause the occlusive member to substantially retain its shape. Examiner respectfully disagrees. The combination of the stretch resistant member of Ken and the drug releasing hydrogel of Rosenthal does in fact result in an "active member" that contracts (when the hydrogel releases the drug) and an "active member" that causes the occlusive member to retain its shape (stretch resisting member of Ken). As stated above and repeated here for convenience, the claimed invention does not require the actual act of the active element contracting to cause the coil to retain its shape since during the act of the active element contracting,

the coil will also be moving and reshaping, thus not retaining its shape. Rather, the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape. In other words it is the "deployed configuration" that causes the occlusive member to retain its shape, not the act of contracting.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731